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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

DEVAN GRINER,

Plaintiff,

vs.

JOSEPH R. BIDEN, in his official capacity as the President of the United States of America; the UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator for the Centers for Medicare and Medicaid Services; MEENA SESHAMANI, in her official capacity as Deputy Administrator and Director of Center for Medicare; and DANIEL TSAI, in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services,

Defendants.

Case No. 2:22-cv-00149-DAK

DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

Hon. Dale A. Kimball

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Defendants respectfully move to dismiss the Complaint, ECF No. 2, for lack of jurisdiction and for failure to state a claim, pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6).

INTRODUCTION

COVID-19 has "overtaken the 1918 influenza pandemic as the deadliest disease in American history." *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). By the time the rule at issue here was issued last November, SARS-CoV-2, the virus that causes COVID-19, had infected over 44 million people, hospitalized more than 3 million people, and claimed more than 720,000 lives in the United States. Those numbers have only grown since. The virus can easily pass from person to person at health care facilities. As a result, the pandemic has been devastating for health care facilities and for patients alike. Fortunately, the vaccines now approved or authorized to protect against COVID-19 are safe and highly effective.

The Secretary of Health and Human Services reviewed this evidence and concluded that action was urgently needed to protect patients from infection with the virus while they receive care in facilities funded by Medicare and Medicaid. Congress has assigned the Secretary a statutory responsibility to ensure that the health and safety of patients are protected in these federally funded facilities. To do so, he issued a rule requiring certain health care facilities, as a condition of their participation in these programs, to ensure that those members of their health care staff who interact with patients, or who have contact with other staff who do so, receive vaccination for COVID-19, absent an exemption. The Secretary calculated that the implementation of the rule would save hundreds, and possibly thousands, of lives each month. The Supreme Court reviewed this rule on an expedited basis, and it held that the Secretary had statutory authority to issue the rule, and that the record supported his finding that the rule was needed to prevent the transmission of the virus that causes COVID-19 within federally funded health care facilities. *Biden v. Missouri*, 142 S. Ct. 647 (2022).

Several months after the Supreme Court's decision, and several weeks after the vaccination rule went fully into effect for facilities in Utah, the plaintiff here, Dr. Devan Griner, brought suit to challenge the validity of that rule. He asserts that the rule exceeds the Secretary's statutory authority, that the rule violates his alleged substantive due process right not to be vaccinated, and that the rule violates equal protection by treating vaccinated and unvaccinated health care practitioners differently. As an initial matter, his Complaint should be dismissed for lack of standing. The vaccination rule does not apply directly to practitioners such as Dr. Griner. Instead, the rule requires certain Medicare- and Medicaid-funded facilities, like the hospitals at which he practices, to develop policies to ensure that their staff are vaccinated or claim an exemption. Dr. Griner does not claim that any hospital has taken any action against him under any policies they have developed under the rule. His failure to make this showing is fatal to his claim to standing. For similar reasons, his claim is not ripe for judicial review.

In any event, his claims lack merit. His challenge to the Secretary's statutory authority to issue the rule is squarely foreclosed by the Supreme Court's decision in *Biden v. Missouri*, and his Tenth Amendment claim is likewise foreclosed by Supreme Court case law that upholds Congress's Spending Clause power to condition federal funds on terms that promote the general welfare. His due process claim is without merit, given the century-old precedent of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), which holds that there is no due process right to refuse vaccinations, even where (unlike here) the government imposes a vaccination requirement on the general population under threat of criminal sanctions. And his equal protection claim is also meritless, as the distinction between vaccinated and unvaccinated health care practitioners does not create a suspect classification, and the Secretary certainly had a rational basis to conclude that vaccinations of health care staff would control the spread of a deadly virus. His Complaint should therefore be dismissed for failure to state a claim.

BACKGROUND

A. Statutory and Regulatory Background

The novel coronavirus SARS-CoV-2 causes COVID-19, a severe acute respiratory disease. 86 Fed. Reg. at 61,556-57. As of the time that the Secretary of Health and Human Services issued the regulation at issue in this case last November, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalizations, and 720,000 COVID-19 deaths had been reported in the United States, *id.*, including over 500,000 cases and 1,900 deaths among health care staff, *id.* at 61,559. It is "the deadliest disease in American history." *Id.* at 61,556. Because SARS-CoV-2 is highly transmissible, it can readily spread among unvaccinated health care workers, and from these workers to patients, in health care facilities, even when standard infection control practices are followed. *Id.* at 61,557 n.16, 61,585 n.210.

Unvaccinated health care workers are at increased risk for SARS-CoV-2 infection, and so for exposing their colleagues and patients to the virus. *Id.* at 61,558 n.42. Due to many of the factors that qualify participants in the Medicare and Medicaid programs for enrollment (e.g., age, disability, and/or poverty), patients in facilities funded by these programs are more likely than the general population to suffer severe illness or death from COVID-19. *Id.* at 61,609. For these reasons, "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS [the Centers for Medicare & Medicaid Services] to take action." *Id.* at 61,558.

Fortunately, the approved or authorized COVID-19 vaccines currently available for use in the United States have been shown to be safe, *id.* at 61,562, and highly effective in preventing serious outcomes of COVID-19, *id.* at 61,565 n.115. They offer strong protection against known variants of the virus, particularly against hospitalization and death. *Id.* at 61,565 n.116. The vaccines are highly effective in preventing SARS-CoV-2 infection among frontline workers. *Id.* at 61,585 n.205. Studies have also shown that vaccinated people with breakthrough infections may be less infectious than

unvaccinated individuals with primary infections, resulting in fewer transmission opportunities. *Id.* at 61,558 n.37 (citing, *e.g.*, Marc M. Shamier et al., *Virological Characteristics of SARS-CoV-2 Vaccine Breakthrough in Health Care Workers* (Aug. 21, 2021), https://perma.cc/R3ZL-N5VU).

To be eligible for federal funding under Medicare, providers such as hospitals voluntarily enter into agreements with CMS if they meet the conditions for participation. 42 U.S.C. § 1395cc. Medicaid providers, likewise, voluntarily enter into agreements with State Medicaid agencies to be eligible for funding under that program. *Id.* § 1396a(a)(27). By entering into the provider agreement, a facility agrees that it will comply with the Medicare and Medicaid statutes and with the regulations issued by the Secretary. *See id.* §§ 1395cc(b)(2); 1396a(p)(1). The Secretary establishes conditions of participation through regulations that address, *inter alia*, providers' obligations to protect the health and safety of patients in their care. *See, e.g.*, *id.* § 1395x(e)(9). For decades, the Secretary has exercised that authority to require participating health care providers to establish programs for the "prevention" and "control" of "infectious diseases" within their facilities. *See, e.g.*, 42 C.F.R. § 482.42.

On November 5, 2021, the Secretary published the interim final rule at issue here, which conditions federal funding under the Medicare and Medicaid programs for certain providers on their agreement to develop and implement plans and policies to "ensure staff are fully vaccinated for COVID-19, unless exempt[.]" 86 Fed. Reg. at 61,561. The rule requires facilities to develop procedures to permit staff to request exemptions for medical, religious, or other reasons, but absent an exemption the rule applies for any staff who are regularly present at a facility and who may "interact with other staff, patients, residents, clients, or [elderly care] program participants in any location[.]" *Id.* at 61,568, 61,570. Given the high transmissibility of the virus, the Secretary concluded that it was necessary to apply his rule broadly enough to cover staff members of health care facilities who may "encounter fellow employees, such as in an administrative office or at an off-site staff meeting, who will

themselves enter a health care facility or site of care for their job responsibilities[.]" *Id.* at 61,568.

The Secretary considered several alternatives, including the option of requiring regular testing for health care staff. He rejected this option after "review[ing] scientific evidence on testing and [finding] that vaccination is a more effective infection control measure." *Id.* at 61,614. In so finding, he relied on studies showing that testing has been less effective in preventing COVID-19 outbreaks, and that certain rapid COVID-19 tests will only detect a fraction of asymptomatic cases. *See* Isaac See et al., *Modeling Effectiveness of Testing Strategies to Prevent COVID-19 in Nursing Homes (COVID-19) in Nursing Homes – United States, 2020*, 73 Clin. Infect. Diseases e792 (Aug. 1, 2021), https://perma.cc/J9QY-AW38; Ian W. Pray et al., *Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2, Testing at Two University Campuses – Wisconsin, Sept. – Oct. 2020*, 69 Morbidity & Mortality Weekly Report 1642 (Jan. 1, 2021), https://perma.cc/HX2P-MVZG.

The Secretary also considered whether to exempt persons with prior SARS-CoV-2 infections under his rule. He reviewed the scientific evidence and concluded that these persons remain at risk of being re-infected with the virus. 86 Fed. Reg. at 61,559. He found that temporary infection-induced immunity is not equivalent to receiving vaccination for COVID-19, *id.*, and that, even among those persons with prior SARS-CoV-2 infections, vaccination provides strong additional protection against reinfection, *id.* at 61,585 n.205. His findings followed the recommendations of the Centers for Disease Control and Prevention (CDC), which support vaccination for all people, regardless of their infection history. *Id.* at 61,560. "Substantial immunologic evidence and a growing body of epidemiologic evidence indicate that vaccination after infection significantly enhances protection and further reduces risk of reinfection." CDC, *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity* (updated Oct. 29, 2021), https://perma.cc/9LTJ-KDD3. The Secretary also found that an exemption for previously infected people would be difficult to administer, as it would require the development

of "standards that do not now exist for reliably measuring the declining levels of antibodies over time in relation to risk of reinfection." 86 Fed. Reg. at 61,614.

The rule initially contemplated that all relevant staff would receive the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, or request or have been granted an exemption under the facility's exemption policies, by December 6, 2021 ("Phase 1"). *Id.* at 61,573. The rule also contemplated that by January 4, 2022, non-exempt staff who are covered by the rule would be fully vaccinated ("Phase 2"). *Id.* In light of litigation developments, the Secretary later exercised his enforcement discretion to modify the timeline for compliance for health care facilities in certain states, including Utah, resulting in a February 14, 2022 deadline for Phase 1, and a March 15, 2022 deadline for Phase 2. *See* CMS, *External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule* (updated Jan. 20, 2022), https://perma.cc/ETC6-CABH.

The scientific community has continued to develop evidence of the efficacy of the COVID-19 vaccines. This evidence continues to show that vaccines protect against infection with the virus that causes COVID-19, and against severe outcomes from that disease. Although fully vaccinated people with a booster shot are better protected than those without a booster, even the latter group is much better protected against the virus than are unvaccinated people. *See* Mark G. Thompson et al., *Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance — VISION Network, 10 States, August 2021–January 2022*, 71 Morbidity & Mortality Weekly Report 139 (Jan. 28, 2022), https://perma.cc/85SP-44AK. The COVID-19 hospitalization rate for unvaccinated adults, even after the emergence of the Omicron variant, is 5 times higher than that for fully vaccinated people without a booster, and 7 times higher than for fully vaccinated people with a booster. *See* CDC, *Rates of Laboratory-Confirmed COVID-19 Hospitalizations by Vaccination Status*, https://perma.cc/Y22H-TMUS.

Vaccines also offer strong protection against reinfection for persons who have previously been infected with SARS-CoV-2. *See* Ian D. Plumb et al., *Effectiveness of COVID-19 mRNA Vaccination in Preventing COVID-19–Associated Hospitalization Among Adults with Previous SARS-CoV-2 Infection — United States, June 2021–February 2022*, 71 Morbidity & Mortality Weekly Report 549 (Apr. 15, 2022), https://perma.cc/GT57-92DQ. The most recent evidence also indicates that the vaccinated are less likely to transmit SARS-CoV-2, including the Omicron variant, than are the unvaccinated. *See* Julia M. Baker et al., *SARS-CoV-2 B.1.1.529 (Omicron) Variant Transmission Within Households — Four U.S. Jurisdictions, November 2021–February 2022*, 71 Morbidity & Mortality Weekly Report 341 (Mar. 4, 2022), https://perma.cc/74S8-AW47; *see also* Frederik Plesner Lyngse et al., *Transmission of SARS-CoV-2 Omicron VOC subvariants BA.1 and BA.2: Evidence from Danish Households*, medRxiv (Jan. 30, 2022) (pre-print), https://perma.cc/FFX3-C3MY.

B. Factual Background

Plaintiff, Devan Griner, is a plastic surgeon. Griner Decl., ¶ 3, ECF No. 17-1. He has not received a COVID-19 vaccine, *id.*, ¶ 13, because he believes that he is "not at risk of infecting others" as a result of his prior infection with SARS-CoV-2, *id.*, ¶ 12. He has admitting privileges at four Utah hospitals, which receive federal funding under the Medicare and Medicaid programs. *Id.*, ¶¶ 10, 14.

Plaintiff filed his Complaint in this action on March 4, 2022. Compl., ECF No. 2. He alleges that the vaccination rule violates his constitutional right to privacy (Count I), deprives him of the equal protection of the laws (Count II), and is *ultra vires* (Count III). *Id.*, ¶¶ 81-114. Plaintiff moved for a preliminary injunction against the implementation of the vaccination rule on April 1, 2022. Mot. for Prelim. Inj., ECF No. 17 ("Pl.'s Mot."). He based his motion solely on the first count of his complaint, alleging that COVID-19 vaccines are not effective in preventing transmission of the virus, and that therefore the rule violates his fundamental right to refuse to be vaccinated. *See id.* at 3.

The vaccination rule does not impose obligations directly on individual practitioners such as Plaintiff. Instead, as noted above, the rule instructs Medicare- and Medicaid-funded health care facilities, as a condition of their participation in these programs, to develop procedures to ensure that their health care staffs either are vaccinated or claim an exemption. *See* 86 Fed. Reg. at 61,561. Plaintiff does not allege in his complaint or in his preliminary injunction motion that any of the hospitals at which he has admitting privileges has taken any action against him in response to the vaccination rule.

STANDARD OF REVIEW

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Under Rule 12(b)(1), the plaintiff bears the burden of proving by a preponderance of evidence that the Court has subject matter jurisdiction. *Celli v. Shoell*, 40 F.3d 324, 327 (10th Cir. 1994). A facial attack on the complaint's allegations as to subject matter jurisdiction questions the sufficiency of the complaint. A court reviewing a facial attack must accept the allegations in the complaint as true. But a party may go beyond allegations contained in the complaint and challenge the facts upon which subject matter jurisdiction depends. *Holt v. United States*, 46 F.3d 1000, 1002–03 (10th Cir. 1995).

Under Rule 12(b)(6), a court may dismiss all or part of a complaint where it fails to state a claim upon which relief can be granted. Although a complaint need not contain "detailed factual allegations," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007), it must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation and internal quotation marks omitted). In other words, a plaintiff must offer sufficient factual allegations to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. In ruling on a motion to dismiss, a court should disregard all conclusory statements of law and consider whether the remaining factual allegations, if true, plausibly suggest the defendant is liable.

Kan. Penn Gaming, LLC v. Collins, 656 F.3d 1210, 1214 (10th Cir. 2011).

ARGUMENT

I. PLAINTIFF LACKS STANDING TO BRING HIS CLAIMS.

A. Plaintiff Has Not Alleged Real or Certainly Impending Injury-In-Fact.

Plaintiff lacks standing because he has alleged neither an actual injury nor a threatened injury that is "both real and immediate." *City of Los Angeles v. Lyons,* 461 U.S. 95, 101–02 (1983). Plaintiff alleges, simply, that "the hospitals in which he has the right to practice receive CMS funding." Compl. ¶ 41. This does not suffice. Although it might suggest that "there is the *possibility* that [the hospitals] will suspend or revoke" Plaintiff's privileges, "[a]n Article III injury … must be more than a possibility." *Essence, Inc. v. City of Fed. Heights*, 285 F.3d 1272, 1282 (10th Cir. 2002). Rather, to demonstrate injury-in-fact, a plaintiff "must show that it 'has sustained or is *immediately in danger of sustaining some direct injury*.'" *Id.* (quoting *City of Los Angeles,* 461 U.S. at 101-02 (emphasis added)). Because Plaintiff has not alleged that any hospital has suspended or revoked his practice privileges, or even discussed with him whether his privileges will continue if he does not obtain vaccination for COVID-19 or a qualifying exemption from vaccination, he has not shown an injury-in-fact. *See Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1229 (10th Cir. 2005) (a plaintiff must show "sufficient 'consequences following from the [challenged provision's] enforcement,' to show an injury in fact").[1]

While a plaintiff "need not 'await the consummation of threatened injury,' [] the injury must be 'certainly impending,'" for standing purposes. *Essence, Inc.*, 285 F.3d at 1282 (quoting *Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298 (1979)). The Tenth Circuit has held that where a

[1] To the extent Plaintiff relies on alleged injury to others (specifically, prospective patients, *see, e.g.*, Compl. ¶ 79), such a claim cannot form the basis of standing. *See, e.g.*, *Bear Lodge Multiple Use Ass'n v. Babbitt*, 175 F.3d 814, 821 (10th Cir. 1999) ("a litigant may invoke only its own constitutional rights and may not assert rights of others not before the court").

plaintiff's claim involves the suspension or revocation of a right or privilege on an allegedly unconstitutional basis, the plaintiff must allege either that a party "has sought to suspend or revoke [the privilege] or has threatened to do so," or "any fact indicating that suspension or revocation may be imminent or that [the plaintiff] has altered its behavior as a result of the [challenged] provision," in order to "carr[y] its burden of demonstrating standing." *Essence, Inc.*, 285 F.3d at 1282 (holding that business license holder lacked standing to bring First Amendment challenge to city ordinance allowing license suspension or revocation in certain circumstances, because plaintiff had alleged neither imminent threat of suspension or revocation nor self-censorship). Because Plaintiff makes no such allegations, his claims must be dismissed for lack of standing.

B. Plaintiff Cannot Demonstrate Causation Or Ripeness For His Claims Because They Rest Upon Contingent Future Events That May Not Occur.

Plaintiff's failure to allege that any hospital has suspended or revoked his practice privileges, or even discussed with him whether his privileges will continue if he does not obtain vaccination for COVID-19, similarly renders his claims unripe. "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotations omitted). Here, Plaintiff's allegation that "the hospitals in which he has the right to practice receive CMS funding," Compl. ¶ 41, does not suffice to show that these hospitals will terminate Plaintiff's practice privileges.

The ripeness inquiry "requir[es] [courts] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). "[W]here 'we have no idea whether or when … [a sanction] will be ordered,' the issue is not fit for adjudication." *Texas*, 523 U.S. at 300 (internal quotation omitted). Plaintiff's claims are not fit for adjudication because he has alleged no facts indicating whether the injury of

which he complains—the termination of his hospital practice privileges—will occur.

The vaccination rule does not directly impose obligations on individual practitioners such as Plaintiff. Instead, the rule applies to certain categories of health care facilities, including hospitals that receive Medicare or Medicaid funding, to require them to develop their own plans and policies to "ensure staff are fully vaccinated for COVID-19, unless exempt." 86 Fed. Reg. at 61,561. Plaintiff does not allege that any hospital at which he practices has attempted to apply any policy to require him to be vaccinated. His claim that the vaccination rule will cause him injury, then, "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300. For example, the hospitals may determine Plaintiff to be exempt, or they may otherwise determine that he is not included in the category of staff to whom a vaccination protocol would apply. Plaintiffs' claim of an injury remains speculative at least until such time as one of the hospitals at which he practices takes some action against him. His claims are, accordingly, unfit for review. *Id.* at 300-01; *see also Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 810 (2003). Similarly, even if a hospital were to take some action against him in the future, it would only be matter of speculation now as to whether that action would be taken as a result of the vaccination rule or as a result of the hospital's own policies; Plaintiff accordingly cannot meet his Article III burden to show that any (at this point hypothetical) injury is traceable to the challenged rule.

Nor would withholding judicial review at this time work any hardship on Plaintiff. His Complaint is devoid of any allegation identifying any scheduled or otherwise upcoming procedure which Plaintiff wishes to perform at one of the identified hospitals. But he suffers no injury "unless and until" he seeks to provide medical care at a hospital at which he has practice privileges and is prohibited from doing so. *Texas*, 523 U.S. at 302 (noting the court's holdings that the abstract "'threat to personal freedom' that exists whenever an agency regulation is promulgated[] … [are] inadequate

to support suit unless the person's primary conduct is affected"). Because Plaintiff alleges no fact suggesting any hospital has yet taken or threatened to take action against him, his claims are unripe.

II. THE COMPLAINT FAILS TO STATE A CLAIM.

A. The Secretary Has Statutory Authority to Issue the Vaccination Rule.

In his preliminary injunction motion, Plaintiff disclaims any challenge to "the rule-making authority of CMS or the Secretary of Health and Human Services." Pl.'s Mot. at 4. Count III of his Complaint, however, asserts that the Secretary lacked the authority to issue the vaccination rule, and that the rule is *ultra vires*. Compl., ¶¶ 110-114, ECF No. 2. This claim is foreclosed by the Supreme Court's recent decision in *Biden v. Missouri*, 142 S. Ct. 647 (2022), which upheld the rule.

The Supreme Court held that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Id.* at 652. The Secretary has the "general statutory authority to promulgate regulations 'as may be necessary to the efficient administration of the functions with which [he] is charged.'" *Id.* at 650 (quoting 42 U.S.C. § 1302(a)). "One such function—perhaps the most basic, given the Department's core mission—is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety." *Id.* "To that end, Congress authorized the Secretary to promulgate, as a condition of a facility's participation in the programs, such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.'" *Id.* (quoting 42 U.S.C. § 1395x(e)(9)). The Court noted that, "[r]elying on these authorities, the Secretary has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds." *Id.* "Such conditions have long included a requirement that certain providers maintain and enforce an 'infection prevention and control program designed … to help prevent the development and transmission of communicable diseases and infections.'" *Id.* at 650-51 (quoting 42 C.F.R. § 483.80).

The Court cited the Secretary's findings that the rule "will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients," and that "a vaccine mandate is necessary to promote and protect patient health and safety in the face of the ongoing pandemic." *Id.* at 652 (citing 86 Fed. Reg. at 61,557-58, 61,613). The Court concluded that

> [t]he rule thus fits neatly within the language of the statute. After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the "very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19."

Id. (quoting *Florida v. Dep't of Health & Hum. Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)). The vaccination rule thus "is a straightforward and predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose." *Id.* at 653. "Vaccination requirements are a common feature of the provision of healthcare in America: Healthcare workers around the country are ordinarily required to be vaccinated for diseases such as hepatitis B, influenza, and measles, mumps, and rubella." *Id.*

The Court also held that the rule is not arbitrary and capricious. The plaintiffs in the cases before the Court, including the State of Utah, had argued that the Secretary acted arbitrarily by imposing a vaccination rule, rather than a testing regime, because, in their view, there was not sufficient evidence that the vaccines were effective in preventing the transmission of the virus that causes COVID-19. They also argued that the Secretary had arbitrarily refused to exempt staff who had previously been infected with SARS-CoV-2. The Supreme Court rejected these arguments:

> Given the rulemaking record, it cannot be maintained that the Secretary failed to "examine the relevant data and articulate a satisfactory explanation for" his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of employees with "natural immunity" from prior COVID-19 illness; and (3) depart from the agency's prior approach of merely encouraging vaccination.

Id. at 653-54; *see also id.* at 654 (the courts' role "is to 'simply ensur[e] that the agency has acted within a zone of reasonableness'") (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).

The Court also held that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered below." *Id.* at 653. These remaining contentions included a claim by the State of Utah and other States that the vaccination rule violated the Tenth Amendment by intruding on their police power over public health matters. *See* Response to Application for a Stay Pending Appeal at 1, 23-27, *Becerra v. Louisiana*, Nos. 21A240, 21A241 (U.S. Dec. 30, 2021). They argued that, at a minimum, the Supreme Court should interpret the statute to avoid the asserted constitutional problems. *See id.* at 27. The Supreme Court nonetheless ruled in the Secretary's favor and interpreted the statute to authorize the rule, effectively disposing of the Tenth Amendment claim as well.

It is unsurprising that the Supreme Court disposed of the constitutional claim so easily. Congress has exercised its authority under the Spending Clause by instructing the Secretary to ensure that federally funded health care facilities protect the health and safety of their patients. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare[.]" *Sabri v. United States*, 541 U.S. 600, 605 (2004). Congress's power to impose conditions on federal funds applies even if Congress legislates "in an area historically of state concern." *Id.* at 608 n.*. Thus, for as long as these programs have been in existence, "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions that address the safe and effective provision of healthcare[.]" *Biden v. Missouri*, 142 S. Ct. at 652.

B. The Vaccination Rule Does Not Violate Substantive Due Process.

Plaintiff alleges in Count I of his Complaint that the vaccination rule violates his substantive due process rights, and he bases his preliminary injunction motion on this ground. This claim is

meritless. Because Plaintiff challenges a generally applicable regulation that the Secretary issued pursuant to a Congressional grant of authority, a "two-part substantive due process framework is applicable." *Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1182 (10th Cir. 2009); *see also ETP Rio Rancho Park, LLC v. Grisham*, 522 F. Supp. 3d 966, 1029 (D.N.M. 2021). First, the Court must "carefully describe the asserted fundamental liberty interest." *Dias*, 567 F.3d at 1181; *see also Washington v. Glucksberg*, 521 U.S. 702, 721 (1997). Second, the Court must then determine whether the asserted right—thus narrowly defined—is "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Dias*, 567 F.3d at 1181. If the challenged government action infringes upon a fundamental right, it receives heightened judicial scrutiny; if not, it receives rational basis review. *Id.*; *see also Valdez v. Grisham*, --- F. Supp. 3d ---, 2021 WL 4145746, at *5 (D.N.M. Sept. 13, 2021), *appeal filed*, No. 21-2105 (10th Cir. Sept. 15, 2021). Here, Plaintiff fails to narrowly define the right at issue, and when the proper claim is in view, no fundamental right is implicated.

1. Plaintiff Asserts a Right to Remain Unvaccinated While Working at Federally Funded Health Care Facilities.

The vaccination rule conditions Medicare and Medicaid funding for health care facilities on their agreement to develop policies to ensure that their staff either receive COVID-19 vaccination or claim an exemption. *See* 86 Fed. Reg. at 61,561. Thus, to the extent that the rule implicates any liberty interest of Plaintiff, it is his interest in remaining unvaccinated from a deadly and highly transmissible disease while treating patients at federally funded hospitals. Under case law that has been in place for more than a hundred years, however, there is no fundamental right to refuse vaccination, even where (unlike here) the government would impose a vaccination requirement on the general population under threat of criminal sanctions. *See Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

Plaintiff attempts to avoid *Jacobson* by asserting that the vaccination rule instead infringes on his "fundamental human right to refuse medical treatments." Pl.'s Mot. 10-13, 15, 18-19 (citing *Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990)). But, in *Cruzan* itself, the Supreme Court cited *Jacobson* for the proposition that any such liberty interest is outweighed by the government's interest in preventing disease by requiring or encouraging vaccinations. *Cruzan*, 497 U.S. at 278; *see also We The Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 293 (2d Cir. 2021). Plaintiff nonetheless insists that the COVID-19 vaccines should be considered to be "medical treatments" rather than "vaccinations" because, in his view, they are ineffective in preventing the transmission of SARS-CoV-2. The central point of *Jacobson*, however, was that the courts lack the institutional capacity to second-guess policymakers in their decisionmaking as to whether vaccines are effective in preventing disease.

The defendant in that criminal prosecution had argued that some doctors did not believe that vaccination would prevent the spread of smallpox. *Jacobson*, 197 U.S. at 30. The Court rejected this claim, explaining that it presumed that policymakers were aware of the competing views of medical experts, and that it was the role of policymakers, not the courts, to evaluate opposing theories as to how best to "meet and suppress the evils of a smallpox epidemic that imperiled an entire population." *Id.* at 30-31. The Court acknowledged the "possibility that the belief [that vaccines were effective] may be wrong, and that science may yet show it to be wrong," but held this was "not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases." *Id.* at 35; *see also Valdez*, 2021 WL 4145746, at *6-7.

Plaintiff, therefore, may not avoid the holding of *Jacobson* by asserting his disagreement with the Secretary's understanding of the evidence. But, in any event, the Secretary had ample grounds—and certainly a rational basis—to conclude that the available vaccines are effective in controlling the spread of SARS-CoV-2. As noted above, *see supra* pp. 4-6, the best reading of the medical literature

that was available at the time that the vaccination rule was issued in November 2021, and the best reading today, show that fully vaccinated people are substantially less likely than unvaccinated people to contract that virus, to spread that virus to others, or to be hospitalized or to die as a result of contracting the virus. Plaintiff may have a different view of the scientific evidence, but "[i]t is no part of the function of a court" to weigh such evidence. *Jacobson*, 197 U.S. at 30. Rather, the evaluation of the relative efficacy of vaccines is "a determination for the [policymaker], not the individual objectors." *Phillips v. City of New York*, 775 F.3d 538, 542 (2d Cir. 2015) (citing *Jacobson*, 197 U.S. at 37-38); *see also Doe v. Zucker*, 520 F. Supp. 3d 217, 251 (N.D.N.Y. 2021); *Valdez*, 2021 WL 4145746, at *8.

Nor does Plaintiff advance his claim by asserting that he cannot "refuse" COVID-19 vaccines. The vaccination rule does not *force* anyone to receive vaccines; personnel who work in federally funded health care settings may choose to receive the vaccine, they may seek an exception based on a medical condition or religious objection, or they may choose to pursue other employment. *Accord We The Patriots USA*, 17 F.4th at 293–94. Because the vaccination rule is not a requirement imposed on the general public, but instead is a condition on federal funding for health care facilities, "this case is easier than *Jacobson*." *Klaassen v. Trs. Of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021). In sum, in "carefully describ[ing]" the liberty interest that is at issue here, *Dias*, 567 F.3d at 1181, this case involves an interest in avoiding vaccination while treating patients at a hospital, not a general right to refuse medical treatment. *See Valdez*, 2021 WL 4145746, at *5 (holding that plaintiffs' "assertion of broadly defined rights falls short of providing the 'careful description'" required, and finding no fundamental right "to work in a hospital … unvaccinated and during a pandemic").

2. The Vaccination Rule Does Not Infringe on a Fundamental Right

With the proper scope of the asserted right set forth, the next step is to determine whether the claimed right is "fundamental" in the American legal tradition. Plaintiff enjoys no fundamental

right to remain unvaccinated while practicing medicine at federally funded health care facilities.

A right to refuse vaccination is not "deeply rooted in this Nation's history and tradition." *Dias*, 567 F.3d at 1181 (quoting *Glucksberg*, 521 U.S. at 720-21) To the contrary, "vaccination requirements, like other public-health measures, have been common in this nation." *Klaassen*, 7 F.4th at 593; *see also Biden v. Missouri*, 142 S. Ct. at 653. The vaccination rule thus does not burden any "fundamental right ingrained in the American legal tradition." *Klaassen*, 7 F.4th at 593; *accord, e.g.*, *Doe v. Zucker*, 520 F. Supp. 3d at 249–53. For this reason, the federal courts have consistently held that vaccine mandates do not implicate a fundamental right. *See Klaassen*, 7 F.4th at 593; *We The Patriots USA*, 17 F.4th at 293–94; *Norris v. Stanley*, No. 1:21-CV-756, 2021 WL 4738827, at *2 (W.D. Mich. Oct. 8, 2021) (unpublished). Nor does the vaccination rule implicate any fundamental right of Plaintiff's to work as a surgeon. As the Tenth Circuit has explained, the asserted "right to practice in [one's] chosen profession … does not invoke heightened scrutiny." *Valdez*, 2021 WL 4145746, at *5 (quoting *Guttman v. Khalsa*, 669 F.3d 1101, 1118 (10th Cir. 2012).

In sum, there is no fundamental right to refuse vaccinations necessary to prevent the spread of communicable diseases. That principle has even more force in the context of the Secretary's narrowly targeted rule, which does not impose a vaccination requirement on the general public, but instead conditions federal funding for health care facilities on their development and implementation of policies to ensure that their non-exempt staff are vaccinated.

3. The Vaccination Rule has a Rational Basis.

Where a substantive due process claim does not implicate a fundamental right, the challenged government action need only survive rational basis review. *Valdez*, 2021 WL 4145746, at *5; *see also Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring) (explaining that *Jacobson* "essentially applied rational basis review" to a vaccination requirement). "[R]ational basis

review is highly deferential toward the government's actions. The burden is on the plaintiff to show the governmental act complained of does not further a legitimate state purpose by rational means." *Seegmiller v. LaVerkin City*, 528 F.3d 762, 772 (10th Cir. 2008). The challenged measure "is presumed constitutional," and "[t]he burden is on the one attacking [it] to negative every conceivable basis which might support it." *Heller v. Doe ex rel. Doe*, 509 U.S. 312, 320 (1993).

The Supreme Court has held that the vaccination rule was "not arbitrary and capricious," and that the Secretary reasonably explained his decisions to (1) "impose the vaccine mandate instead of a testing mandate," (2) "require vaccination of employees with 'natural immunity' from prior COVID-19 illnesses;" and (3) "depart from the agency's prior approach of merely encouraging vaccination." *Biden v. Missouri*, 142 S. Ct. at 653-54. Because the Supreme Court held that the rule is not arbitrary and capricious, it necessarily follows that the rule is rational for purposes of due process review. *See Ursack Inc. v. Sierra Interagency Black Bear Grp.*, 639 F.3d 949, 958 (9th Cir. 2011) (holding that "rational basis scrutiny" is "identical to arbitrary and capricious review under the APA"). The Secretary plainly had a rational basis to conclude that COVID-19 poses a serious threat to the health and safety of patients at Medicare- and Medicaid-funded facilities, and that the vaccination of health care staff would help to protect those patients. *See supra*, pp. 3-6; *see also, e.g.*, *Valdez*, 2021 WL 4145746, at *6.

Plaintiff also contends that the vaccination rule is not narrowly tailored because it does not exempt persons who were previously infected with SARS-CoV-2. Pl.'s Mot. 16-18. The Supreme Court has already rejected this argument, finding that the Secretary had reasonably explained his decision not to provide for such an exemption. *Biden v. Missouri*, 142 S. Ct. at 653. In any event, "rational-basis review does not give courts the option to speculate as to whether some other scheme could have better regulated the evils in question." *Powers v. Harris*, 379 F.3d 1208, 1217 (10th Cir.

2004). Put another way, rational basis review contains no tailoring requirement. *Reno v. Flores*, 507 U.S. 292, 305 (1993) ("[N]arrow tailoring is required only when fundamental rights are involved.").

Plaintiff similarly fails in recasting his claim as one challenging an "unconstitutional condition." *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013) ("[T]he unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them."). In order to state a claim under this doctrine, Plaintiff must identify a constitutional right that he is being coerced to give up. *Petrella v. Brownback*, 787 F.3d 1242, 1265 (10th Cir. 2015) ("The doctrine only applies if the government places a condition on the exercise of a constitutionally protected right."). But as explained above, Plaintiff cannot point to any such right. *See, e.g., Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017). Therefore, courts have uniformly rejected claims that vaccination requirements subject plaintiffs to unconstitutional conditions. *See, e.g., Doe v. Zucker*, 520 F. Supp. 3d at 268; *Norris v. Stanley*, 2021 WL 4738827, at *3 (unpublished); *Smith v. Biden*, No. 1:21-CV-19457, 2021 WL 5195688, at *8 (D.N.J. Nov. 8, 2021) (unpublished). Plaintiff's substantive due process claim should accordingly be dismissed.

C. The Rule Does Not Deprive Plaintiff of the Equal Protection of the Laws.

In Count II (but not in his motion), Plaintiff raises a claim under the Fifth Amendment's equal protection component, asserting that the vaccination rule improperly discriminates against the "class" of unvaccinated healthcare workers, and favors vaccinated workers. This claim lacks merit as well.

"'[U]nless a legislative classification either burdens a fundamental right or targets a suspect class, it need only bear a rational relation to some legitimate end to comport with' equal protection." *Curley v. Perry*, 246 F.3d 1278, 1285 (10th Cir. 2001). As explained above, the vaccination rule infringes on no fundamental right, and a rule that distinguishes between vaccinated and unvaccinated health care professionals does not draw lines on the basis of a suspect or quasi-suspect

class. *See Save Palisade FruitLands v. Todd*, 279 F.3d 1204, 1210 (10th Cir. 2002) (listing suspect and quasi-suspect classes). The equal protection claim is therefore also subject only to rational basis review. *See Valdez*, 2021 WL 4145746, at *9.

And for the same reasons that the vaccination rule is rational for purposes of substantive due process, it is also rational in the context of equal protection. *See Powers v. Harris*, 379 F.3d at 1215 (rational basis review under due process and under equal protection "proceeds along the same lines"). It is plainly reasonable for the Secretary to distinguish between the vaccinated and unvaccinated because the latter are significantly more likely to contract, spread, be hospitalized for, and die of COVID-19. For this reason, courts have uniformly rejected equal protection claims challenging COVID-19 vaccination requirements. *See, e.g., Does 1-6 v. Mills*, 16 F.4th 20, 35 (1st Cir. 2021), *cert. denied*, 142 S. Ct. 1112 (2022); *Kheriaty v. Regents of Univ. of Cal.*, No. SACV-21-01367-JVS (KESx), 2021 WL 4714664, at *7 (C.D. Cal. Sept. 29, 2021) (unpublished); *Valdez*, 2021 WL 4145746, at *9.

CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiff's Complaint.

Dated: April 21, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2022, I filed the foregoing Motion to Dismiss with the Clerk of the Court electronically via the Court's ECF system which sent notification of such filing to counsel of record for all parties.

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